APR 2 4 2014
K133870

5. 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for Coleman Laboratories' Fluid Level Monitor 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information upon which the substantial equivalence determination is based.

1) Submitter Information

Company Name:	Coleman Laboratories
Company Address:	1150 First Avenue, Suite 501 King of Prussia, PA 19406, USA
Contact:	Le-Jun Yin, Vice President, Product Management
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Date Summary Prepared:	December 18th, 2013

2) Device Identification

Generic Device Name:	Electronic I.V. Monitor
Trade/Proprietary Name:	Fluid Level Monitor Model
Numbers:	LM771, LM781, LM785
Classification:	Class II
Panel:	General Hospital (80)
Regulation Number:	21 CFR 880.2420
Regulation Name:	Electronic monitor for gravity flow infusion systems
Product Code:	FLN
510(k) Number:	K133870

3) Predicate Device

510(k) Number:	K030136, K903193
Trade Name:	Drip Alert, Levelert
Product Code:	FLN

4) Description of Device

Fluid Level Monitor is a passive sensing device that alarms when the infusion fluid level is low. Fluid Level Monitor provides both visual and audible alarms when preset condition is met. Fluid Level Monitor operates on DC power source.

Fluid Level Monitor includes both main control unit and external sensor. There are status LEDs on the main control unit to display run, alarm and battery-low status. There is a buzzer on the main control unit to provide audible alarm.

The external sensor is connected to the main control unit via shielded signal cable. The sensor can be clipped on the tubing to monitor fluid level.

5) Intended Use

The Fluid Level Monitor is a passive sensing device that alarms when the infusion fluid level is low. The device provides both visual and audible alarms when preset condition is met.

The Fluid Level Monitor is intended for low-fluid-level alarm use in any healthcare setting where gravity flow infusion is utilized. The use of the device improves efficiency within a busy medical setting by providing healthcare personnel of timely notification of the low-fluid-level status. The available models are:

LM771: 1-channel, DC battery power
LM781 1-channel, DC plug-in power

LM785 5-channel, DC plug-in power

6) Comparison of Technical Characteristics

Coleman Laboratories' Fluid Level Monitors (3 Models) are substantially equivalent to the predicate devices:

K030136 - Drip Alert, Drip Alert, Inc.
K903193 - Smith & Nephew, Inc.

They have the same design principles, material, indications for use, and intended use.

Device Name	Fluid Level Monitor			Drip Alert	Levelert
Device Model	LM771	LM781	LM785	-	-
510(K) Number	K133870			K030136	K903193
Passive device	Yes	Yes	Yes	Yes	Yes
Uses a processor to perform measurements	Yes	Yes	Yes	Yes	Yes
Use sensor to detect fluid-level-low status	Yes	Yes	Yes	Yes	Yes
Visual and audible alarm on fluid-level-low status	Yes	Yes	Yes	Yes	Yes
Patient has no contact with device	Yes	Yes	Yes	Yes	Yes
Class II device	Yes	Yes	Yes	Yes	Yes
Power source	DC battery	DC plugin	DC plugin	DC battery	DC plugin
Monitoring Point	1	1	5	1	1

7) Summary Performance Data

Based on the risk analysis, the verification and validation tests that were performed and the acceptance criteria applied for each are listed in Section 18. Performance testing was conducted to confirm compliance to design specifications; all functions were verified to operate as designed.

The performance test data demonstrated that the system power consumption remains same when using:

a) DC battery or DC plug-in power
b) 1-channel or 5-channel sensing

We concluded that the design difference on number of monitoring points does not raise safety or effectiveness concerns.

8) Conclusion

Based on the analysis on nonclinical test data, and comparison on design principle, operation procedure and indications for use, we demonstrated that the device is as safe, as effective, and performs as well as the predicate devices. The design difference does not raise questions on safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 24, 2014

Coleman Laboratories
Le-Jun Yin
Vice President, Product Management
1150 First Avenue, Suite 501
King of Prussia, PA 19406, USA

Re: K133870
Trade/Device Name: Fluid Level Monitor, Models LM771, LM781, and LM785
Regulation Number: 21 CFR 880.2420
Regulation Name: Electronic monitor for gravity flow infusion systems
Regulatory Class: II
Dated: March 13, 2014
Received: March 28, 2014

Dear Mr. Yin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Erin I. Keith, M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement on last page.

510(k) Number *(if known)*
K133870

Device Name
Fluid Level Monitor, Models LM771, LM781, and LM785

Indications for Use *(Describe)*
The Fluid Level Monitor is a passive sensing device that alarms when the infusion fluid is low. The device provides both visual and audible alarms when preset condition is met.

The Fluid Level Monitor is intended for low-fluid-level alarm use in any healthcare setting where gravity flow infusion is utilized. The use of the device improves efficiency within a busy medical setting by providing healthcare personnel of timely notification of the low-fluid-level status.

LM771: 1-channel, DC battery power
LM781: 1-channel, DC plug-in power
LM785: 5-channel DC plug-in power

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Sajjad H. Syed -S

Digitally signed by Sajjad H. Syed -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Sajjad H. Syed -S, 0.9.2342.19200300.100.1.1=2000601742
Date: 2014.04.24 12:11:28 -04'00'